

## **R E M A R K S**

### **Status of the claims**

Claims 1, 2, 5, 6, 9, 11, 12, 19-21, 24, 29, 31, and 33-37 are pending in the application with claims 21, 24 and 31 being amended herein and claims 36 and 37 being newly added. Support for new claim 36 may be found on page 44, line 11 through page 45, line 2 of the specification. Support for new claim 37 may be found on page 20, line 13-14. No new matter has been added by the amendments or new claims. As such, entry thereof is respectfully requested.

### **Rejections under 35 U.S.C. §112, 1<sup>st</sup> paragraph**

*Claims 1, 2, 5, 6, 9, 11, 12, 18-20, 29, 31 and 33-35 –*

Claims 1, 2, 5, 6, 9, 11, 12, 18-20, 29, 31 and 33-35 have been rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph for lacking enablement. The Examiner takes the position that the specification is enabled for:

- i) the extracellular domain of SEQ ID NO:2
- ii) the full length sequence of SEQ ID NO:2
- iii) isolated nucleic acids encoding i) and ii)
- iv) vectors and transformed host cells containing the nucleic acids of iii)

In response to the comments and evidence submitted on April 19, 2006, the Examiner asserts that the evidence presented thus far supports that antibodies that recognize the extracellular domain of SEQ ID NO:2 induce G-CSF.

The Examiner notes that the recitation of hybridizing sequences results in the claims encompassing proteins that have non-conservative changes in the amino acid sequence. The Examiner further relies on McGuiness (1991) and Daniel (1994) as showing the unpredictability in the art. On page 5, the Examiner further relies upon Wells (1990) and Ngo (1994) as teaching that certain regions of a protein are critical for maintaining antigenicity. The Examiner asserts that the specification fails to provide any guidance as to what changes may be made to the protein while still maintaining proper antigenicity. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

Applicants note that the Examiner is relying on references that pre-date the instant invention by at least 5-10 years. The field of molecular biology advanced dramatically in the period from the 10 years spanning the late 1980's/early 1990's through the late 1990's/early 2000's. As such, the references relied upon by the Examiner are not contemporaneous with the instant invention and therefore are not probative of the enablement of the invention or lack thereof, as asserted by the Examiner.

In addition, the protein of the instant invention as encompassed by SEQ ID NO:2 does not share homology with other known proteins, and the specification describes the identification of a human homolog having 84.8% identity on a DNA level and 93.8% identity on the amino acid sequence level. The person of ordinary skill in the art in 1999, i.e. an MS or PhD level scientist would reasonably expect and could readily confirm that a protein variant having a high identity, such as 90% sequence identity, through only routine experimentation retains the recited activity of the claims. As such, the invention as claimed is fully enabled and withdrawal of the rejection is respectfully requested.

Claims 21 and 24 - Claims 21 and 24 have been further rejected for lacking enablement.

**a) Claim 21** – In the Office Action it is asserted that the screening method of claim 21 would only work if the protein of SEQ ID NO:2 is a receptor, which when activated, induces G-CSF production. It is further asserted that there is no evidence provided that the protein of SEQ ID NO:2 acts as a receptor and that while it has been shown that antibodies that bind to the extracellular domain of SEQ ID NO:2, “there is no evidence that these antibodies achieve their effect by activating the protein of SEQ ID NO:2”. The Examiner states that the antibodies could be antagonizing the SEQ ID NO:2, which would mean that the protein of SEQ ID NO:2 is actually an inhibitor of G-CSF induction.

Claim 21 has been amended to recite:

A screening method for a substance, which can bind to the protein according to claim 9 or the receptor according to claim 20, which comprises:

- (i) providing a potential substance;
- (ii) exposing the potential substance to said protein or receptor; and
- (iii) testing for specific binding.

Thus, claim 21 has been amended to be more specifically directed to a screening method based on the binding between the candidate substance and the protein/receptor of the invention. Applicants believe that the amendments to claim 21 redirect the claim as suggested by the Examiner and withdrawal of the rejection is respectfully requested.

**b) Claim 24** – Claim 24 has been rejected for lacking enablement with the assertion that a pharmaceutical composition has not been enabled because the function of the protein has not been identified. As such, one skilled in the art would not know how to use the pharmaceutical composition of claim 24. Claim 24 has been amended as suggested by the Examiner and the term “pharmaceutical” has been deleted from the claim. Withdrawal of the rejection is therefore respectfully requested.

**Obviousness-type double patenting**

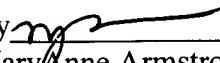
The claims have been rejected under the doctrine of obviousness-type double patenting over claims 1-4 and 18-23 of co-pending application No. 10/381,710. Submitted concurrently with the present response is a terminal disclaimer filed in view of the ‘710 application. Withdrawal of the rejection is respectfully requested.

As the above amendments and remarks address and overcome the rejections, withdrawal thereof and allowance of the claims are respectfully requested. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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